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510(k) Summary for the Medtronic AVE Bridge Aurora Biliary Stent System

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Medtronic AVE, Inc. Peripheral Technologies 3576 Unocal Place Santa Rosa, California 95403
Contact Person	John Riolo Vice President, Regulatory Affairs and Quality Assurance Phone: (707) 541-3271 FAX: (707) 566-1159 e-mail: john.riolo@medtronic.com
Date Prepared	June 20, 2002
Trade Name	Medtronic AVE Bridge Aurora Biliary Stent System ("Aurora")
Common Name	Biliary Stent and Delivery System
Classification Name	Biliary Catheter and Accessories
Device Classification	Classification: Class II Classification Panel: 78FGE Regulation Number: 21 C.F.R. §876.5010
Predicate Device	Bridge SE (K011080, K014205)
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act

510(k) Summary for the Medtronic AVE Bridge Aurora Biliary Stent System

Device Description	The subject device is a system consisting of a single-lumen, tubular, self-expanding nickel-titanium ("nitinol") stent pre-loaded onto a sheathed delivery catheter. The stent design incorporates radiopaque markers to aid in stent placement during fluoroscopy. The delivery system is designed to deliver the stent to the stricture site. Once positioned at the stricture site, the sheath is withdrawn and the stent is released. Upon release, the stent expands and conforms to the inner lumen of the biliary duct. Two catheter mounted radiopaque markers aid in visibility during fluoroscopy.
Indications for Use	The Aurora is indicated for use in the palliation of malignant neoplasm in the biliary tree.
Technological Characteristics	The Aurora is substantially equivalent to the currently marketed Bridge SE. The subject and predicate stents are technologically similar and are intended for palliation of malignant neoplasms in the biliary tree. The subject and predicate stents are constructed of biocompatible materials. The subject and predicate stents are delivered via a sheathed delivery system. The subject device offers increased visibility under fluoroscopy. The subject and predicate stents are comparable and are intended to meet clinical needs. The difference between the subject and predicate devices are minor and are not relevant to the ability of the subject device to palliate malignant neoplasms in the biliary tree.
Nonclinical Performance	Preclinical testing was conducted to confirm the safe and effective performance of this device as well as the biocompatibility of the device.
Sterilization	The Aurora is provided sterile. The device is not intended for reuse or resterilization.
Conclusion	The Aurora is substantially equivalent to the currently cleared and marketed device and meets the clinical needs of the physicians.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2002

Mr. Kevin Drisko
Regulatory Affairs Manager
Medtronic AVE, Inc.
Medtronic Peripheral Technologies
2170-A Northpoint Parkway
SANTA ROSA CA 95407

Re: K022026
Medtronic AVE Bridge Aurora Biliary Stent System
Regulatory Class: II
21 CFR §876.5010
Product Code: 78 FGE
Dated: June 20, 2002
Received: June 21, 2002

Dear Mr. Drisko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

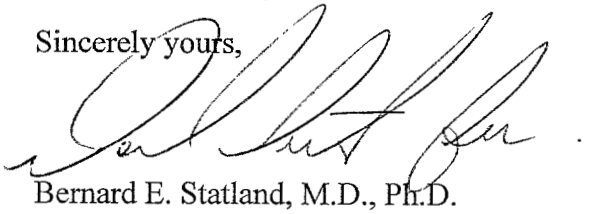
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022026

Device Name: Medtronic AVE Bridge Aurora Biliary Stent System (Aurora)

FDA's Statement of the Indications For Use for device:

The Aurora is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022026